1,093,599

PATENT SPECIFICATION

DRAWINGS ATTACHED

1,093,599

Date of Application and filing Complete Specification March 26, 1965.
No. 12833/65.

Application made in Germany (No. S 90269 IXd/30d) *on March* 26, 1964.

Complete Specification Published December 6, 1967.

Index at Acceptance: Class A5, RBX15.
Int. Cl.: A 61 f 1/00

Improvements in artificial cardiac valves.

COMPLETE SPECIFICATION

I, WOLFGANG SEIDEL, a German National, of 20, Nussbaumstrasse, Munich, Germany, do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The invention relates to artificial cardiac valves, which can be inserted in a living body in place of natural cardiac valves.

One or more of the valves of the human heart may be so gummed up, altered or calcified by illness that a repair is no longer possible by ordinary surgical means. In such cases, grafting of artificial heart valves has been tried for some years with relatively good results. On the basis of a number of technical and clinical observations and animal experiments, it has proved that, in the present state of the art, ball valves are most suitable for this purpose. Of foremost importance is their particularly long working life on account of the minimum stress on the materials used. At the same time they have also usually relatively favourable haemodynamic properties. Basically, however, other types of valves are also applicable.

Known artificial cardiac valves of this kind have a valve body with a base ring, a movable valve member disposed in this body and a sewing ring with a flexible pad fixed on the base ring.

The insertion is effected in this case by holding the prosthesis by means of twenty to thirty separate sutures, each separate thread being first passed through the tissue of the natural valve ring of the heart and then through the pad of the sewing ring provided for this purpose. This process is intricate and requires much time because of the construction of the prosthesis. This is expensive, however, since the circulation of the patient's blood has simultaneously to be maintained by a heart-lung machine in order to ensure a working area in the heart free from blood. In heart surgery success frequently depends on speed.

According to the present invention an artificial heart valve comprises a valve body, a valve member movable with respect to the valve body and a fixing ring serving for fastening the prosthesis to the heart tissue, the fixing ring being initially separate from but being capable of being united with the valve body. The valve body and the fixing ring are inserted separately in the heart and are finally united on the spot, in order to complete the insertion of the valve.

The fixing ring and the valve body may be permanently united, for example, by glueing or welding. It is often advantageous, however, especially for experimental work on animals, for the connection between the two parts to be made detachable, for example by a screw connection, plug and socket connection or a bayonet connection.

In a preferred embodiment of the invention, the fixing ring is attached as such to the natural heart tissue. In such a case it is first connected alone to the natural valve tissue, unhindered by the valve mechanism and consequently very quickly: for example, it is stitched or firmly hooked. As soon as this is done, the valve body is united with the fixing ring, an operation which, since the connection of two mechanical parts is concerned, can naturally take place in a matter of seconds.

The fixing ring may be provided with a number of recesses distributed over its periphery, through which a surgical thread for stitching the fixing ring to the natural heart tissue can be passed. It is possible by this means to attach the fixing ring to the natural valve tissue by a single thread in a continuous seam. This can take place in a fraction of the time which is required

for putting into place the numerous separate stitches in the case of the known prosthesis construction.

In a modified embodiment of the invention, the fixing ring is also provided with spikes which can be clamped to the natural heart tissue. In such case a seam can be dispensed with.

Glueing of the fixing ring to the natural tissue is also possible, in which case the parts of the fixing ring facing the tissue are suitably roughened. In experiments a substance No. 910 of Eastman was used as adhesive.

Instead of joining the fixing ring directly to the natural tissue, in another modified form of the invention the fixing ring and parts of the valve body may form a built-in annular chamber, which encompasses the natural tissue immediately adjoining the prosthesis and/or a supporting ring joined to the natural tissue, and thus holds the prosthesis. The supporting ring used in some cases may, for example, be stitched, clamped or glued to the natural tissue.

In order to unite the valve body with the fixing ring, the valve body may suitably be provided with a connecting piece cooperating with the fixing ring and having a smaller external diameter than a base ring of the valve body. The diameter of the connecting piece may be chosen so that the fixing ring fitted thereon does not project over, or not substantially over, the external diameter of the base ring of the valve body determining the valve opening. While in the above described known form of the artificial cardiac valve, the openings present in the natural heart are lost to a considerable extent for the effective diameter of the artificial heart valve through the sewing ring placed around the base ring of the valve body, these natural openings can be utilised to the maximum with a heart valve in accordance with the invention. With the same effective opening diameter of the valve, the artificial cardiac valve according to the invention can in consequence have a total diameter about 25% smaller than the known prosthesis. It is thus possible for the surgeon to select with a given valve opening in the heart a substantially larger and therefore more efficient heart valve which, apart from this, causes less injury to the structure of the natural valve ring and its function than the comparatively substantially thicker annular seam of the known prosthesis. The effective diameter of the valve can therefore be so large that even with a heavy body load or stress, the then considerably increased flow rate can be passed through without hindrance, i.e. without substantial prevalvular rise in pressure. Tests have indicated, that, for example, with a ball valve with a ball diameter of 25 mm. the known heart prosthesis has a total diameter of about 40 mm, but a heart valve prosthesis can be constructed in accordance with the invention with a total diameter of only about 30 mm. With the same external diameter, the effective valve opening is thus about doubled.

A constructively simple, reliable union of fixing ring to the connecting piece can be obtained by providing the fixing ring or the connecting piece with flexible barbs, which can be engaged in corresponding depressions in the connecting piece or fixing ring respectively.

In a preferred form, the part of the fixing ring facing the valve member is divided into springy prongs by axial notches which carry at their free ends barb-like projections directed radially inwards, and on its side facing towards the valve member, the connecting part of the valve body is provided with an encircling groove for the reception of the projections of the springy prongs on the fixing ring.

The outer surface of the connecting projection from the free end to the end adjacent the valve member may suitably be broadened out in the general shape of a frusto-cone, so that the springy prongs are placed under stress when the fixing ring and valve body are united.

In the case of a detachable connection between the fixing ring and valve body, safety devices are preferably provided which hold the fixing ring connected to the valve body even if the actual joining instrumentalities should become slack or fall out in some other way. In the above-described form of a fixing ring with springy prongs, whose projecting noses engage in a groove of the connecting projection on the valve body, these safety devices advantageously may have the form of one or more additional safety grooves.

In embodiments in which the fixing ring is stitched to the natural heart tissue, the external diameter of the connecting projection and the internal diameter of the fixing ring may be suitably so proportioned that the surgical thread taken round the fixing ring is clamped firmly between both members on fastening them together. In this way of loosening of the seam is prevented if the thread should chafe through or break for other reasons at one place or another.

Since in the present state of the art even the most modern surgical suture material is not absolutely to be trusted when it is embedded in natural tissue over the years, a material containing meshes or pores is preferably attached to the fixing ring and/or the base ring of the valve body, the meshes or pores of which give to the

natural tissue the opportunity to grow into them. The final safe fixing of the prosthesis thereby takes place through the natural tissue, i.e. the organism itself. In the forms of the prosthesis in which no stitches need to be made, in which, for example, the fixing ring is clamped to the natural tissue, use is also suitably made of the possibility of this additional fixation of the prosthesis by the natural tissue. The supporting ring used in some cases is also preferably provided with such mesh- or pore-containing material.

The meshes or pores should be so wide that the natural tissue has sufficient room to grow into them, together with its blood vessels. Mesh or pore widths of 1/20 to ½ mm have proved specially suitable. In practice a polytetrafluoroethylene fabric (Registered Trade Mark Teflon) of the firm US Catheter and Instrument Corp. with the name "Harrison's interlocked mesh of Teflon No. 3050" has proved satisfactory. Larger widths of mesh could likewise be used, in which case a material, for example collagen, later synthesised by the organism, is preferably inserted in the meshes. In addition to synthetic fabrics, foam plastics with open cells are also suitable for this purpose, which for example, may be glued or welded on the parts of the fixing ring, valve body or supporting ring concerned.

In the preferred form of the invention, the mesh material may partly envelope the fixing ring and be twisted together or folded to a loose pad on the outside of the fixing ring, in which case it is suitably held together by a simple turned over or inward seam. In this case the fixing ring has preferably on the side remote from the base ring, a radially outwardly directed annular flange and the pad is held in the angle between the flange and the axial part of the fixing ring.

The formation of clots on the low pressure auricle side of the prosthesis, which is particularly dangerous in the region of the surgical suture, may be obviated by introducing on the outside of the radial annular flange of the fixing ring or the mesh or pore material there present an anti-coagulant plastic substance preventing the accumulation of fibrin. Silicone rubber, for example, has been found suitable for this.

Also as a protection against clots, a screen may be provided which can be clamped between the base ring and the fixing ring or connected to one of these parts, which screen covers parts of the fixing ring and/or the base ring, the surgical suture and parts of the auricle wall of the heart.

Experiments on animals indicated that clotting in the heart grows along wires and similar rigid structures and thereby separates round these. The clots grow more quickly and more extensively in the part of the ventricle turned away from the main blood stream. When ball valves are used in which the ball is held by a ball cage made up of three or more supporting struts, each of these struts forms a potential seed rail for the growth of clots. Since, as was further found, such clots always start from the wall of the heart or a place on the seam, the formation of clots may be prevented by ending one or more of the struts of the ball cage at a distance from the base ring.

The invention will be further described by way of example, with reference to the accompanying drawings, in which:—

Fig. 1 is a perspective representation of a preferred form of a heart valve prosthesis constructed in accordance with the invention in the assembled state, parts of the base ring and the fixing ring being cut away in order to show their structure;

Fig. 2 is an axial section of the heart valve prosthesis of Fig. 1 but in the unassembled state and without the fixing ring being enveloped by mesh material;

Fig. 3 is a detail section of the heart valve prosthesis of Fig. 1;

Fig. 4 shows the method of attaching the fixing ring of the heart valve prosthesis of Figs. 1 to 3 to the natural tissue;

Fig. 5 is a section similar to Fig. 3 of a modified embodiment of the heart valve prosthesis according to the invention;

Fig. 6 is a section similar to those of Figs. 3 and 5 of a further modified form of the heart valve prosthesis,

Fig. 7 is a fragmental perspective representation of the fixing ring of the heart valve prosthesis of Fig. 6;

Fig. 8 is a section similar to those of Figs 3, 5 and 6 of a further modified form of heart valve prosthesis according to the invention; and

Fig. 9 is a fragmental perspective representation of the fixing ring of the heart valve prosthesis of Fig. 8.

The heart valve prosthesis shown in Figs. 1 and 2 has a valve body 1, made for example, of highly polished corrosion-resistant metal, with a base ring 2, the inner face of which forms a seating 3 for a ball valve 4. The ball valve 4, made for example of silicone rubber, is held freely movable in a ball cage, which is formed from two substantially U-shaped cage struts 6, 7. The struts 6, 7 are each firmly connected by one end to the base ring 2, encircle the ball valve 4 and cross one another, and their other ends form rounded points 8, which are at a certain axial distance (of the order of some millimetres)

from the base ring 2. On the side remote from the ball cage, the base ring 2 carries a connecting projection 9, the inner face of which blends smoothly into the valve seating 3 and the outer side of which, as clearly seen in Fig. 3, tapers in a slightly frusto-conical form from the base ring to the free end of the connecting projection. In the region adjoining the base ring, two annular grooves 10, 11 with a saw-tooth-like cross section are formed one after the other in the axial direction in the outside of the connecting projection 9.

A fixing ring 14, made for example of stainless steel and constructed as an independent component, has a cylindrical portion 15, which has a radial annular flange 16 at its end remote from the valve body 1. The portion 15 of the fixing ring is sub-divided into a plurality of springy prongs 18 by axial notches 17, barb-shaped noses 19 are formed on the free ends of the prongs facing the valve body 1 and are directed radially inwards.

As shown in Figs. 1, 3 and 4, the portion of the fixing ring 14 remote from the valve body 1 is encased with a preferably coarse-mesh synthetic fabric 21, for example netted polytetrafluoroethylene. The lower part of the springy prongs 18 is thus visible through holes or meshes of the fabric and lies free.

The ends of the fabric 21 are collected in the angle formed by the annular flange 16 and the outer side of the cylindrical section 14 and are rolled into a light, loose pad 22, which is held together by means of a strong thread.

For fastening the prosthesis in the heart, the fixing ring 14 is united with the natural heart tissue H by means of a so-called continuous seam. For this purpose a needle N with a surgical thread F (Fig. 4) is first taken from above to the inside round the fixing ring 14 and then is passed out from the ventrical through the natural tissue H to the auricle. When the suture is tightened, the thread F is inserted in the notches 17 between adjacent springy prongs 18 and at the same time the natural tissue H is pushed away from the noses 19 of the springy prongs and pressed against the angle formed by the cylindrical portion 15 and the annular flange 16 of the fixing ring as well as the pad 22.

The valve body 1 with the valve ball 4, attached to a thread and inserted into the ventricle before the sewing in of the fixing ring 14, is then drawn on to the fixing ring by means of the thread. The connecting piece 9 is pushed into the fixing ring 14 and the noses 19 are engaged in the groove 11 by simple strong pressure. In so doing the springy prongs 18 are spread radially outwards owing to the conical construction of the connecting projection 9, through which safe seating of the valve body 1 is ensured. The locking mechanism is not released under any circumstances by the forces occurring in the heart; on the contrary the noses 19, owing to their barb-like form, are only pressed still more firmly into the groove 11 by the pressure formed in the ventricle and weighing on the prosthesis on each contraction of the heart. In case the noses 19 of one or more springy prongs 18 should become disengaged from the groove 11 under extraordinary stresses, the second groove 10 is provided for safety's sake, which if necessary would catch the noses 19 slipping out of the groove 11.

In experiments on dogs, for the implantation of a heart prosthesis of the above-described kind, only half of the time required for attaching known heart valves is needed.

In order to safeguard the surgical thread joining the fixing ring to the heart tissue, the edges of the springy prongs 18 along the notches 17 are preferably polished till rounded.

This in conjunction with the padding out by the synthetic fabric 21 avoids chafing through of the thread. Apart from this, the free space remaining between the fixing ring and the connection projection when the fixing ring is in position is suitably chosen so that the surgical thread passed through this space is tightly clamped. Should the thread chafe through at a particular place or break from other reasons, this does not result in a loosening of the whole seam.

Instead of a continuous seam, separate stitches may obviously be used for fastening the fixing ring 14, which is still done more simply and quicker than the fastening of the usual heart valves.

The final safe fixing of the heart valve is effected later by the natural tissue growing into the synthetic fabric 21.

The heart valve prosthesis shown in Fig. 5 differs from that of Figs. 1 to 4 essentially in that a separate sewing ring 23 is provided, which consists of a solid framework (a metal ring 24 in the example shown) and a porous fabric 25 placed round this framework.

The sewing ring 23 is separately connected to the natural tissue H by means of a continuous seam F. From the one side of the sewing ring (the lower in Fig. 5) the connecting projection 9 of the valve body 1 is then pushed into the sewing ring, and from the other side (the upper in Fig. 5) the fixing ring 14 is pushed into the sewing ring. The noses 19 of the springy prongs 18 of the fixing ring thereby en-

gage in the encircling grooves 10, 11 of the connecting projection 9, while the annular flange 16 of the fixing ring 14 and a broadened shoulder 26 of the base ring 2 lie on both sides round the sewing ring 23, by which the valve is held in place. A screening ring 27, of T-shaped cross section, is clamped by its cylindrical part 28 between the connecting projection 9 and the fixing ring 14 and its flanged part 29 covers the part of the connecting piece, the fixing ring and the surgical suture on the auricle side, as well as parts of the auricle wall, for the purpose of preventing the formation of clots.

It is obvious that the screen 27 could also be placed firmly against the connecting projection or the fixing ring.

In the form of the heart valve prosthesis shown in Figs. 6 and 7, the base ring 2 is provided additionally with a cylindrical part 31 arranged coaxially with the connecting projection 9. Two pairs of grooves 32, 33 of semicircular cross section are formed respectively in the outer face of the connecting projection 9 and in the inner face of the cylindrical part 31, said grooves lying opposite each other in pairs. A flexible spring ring 35 is inserted in each of the grooves 32, 33. The fixing ring 14 has a radial annular flange 36 and a plurality of pins 37 which extend in an axial direction and are connected to the radially inside-lying region of the annular segment 36. Each pin 37 is provided with two annular grooves 38, in which, when the prosthesis is assembled, the spring rings 35 engage and rest.

The annular flange 36 of the fixing ring 14 is provided with an annular pad 39 made of meshed fabric. A further porous annular pad 40 with an L-shaped cross-section surrounds the outer face of the cylindrical part 31 and a supporting shoulder 41 of the base ring 2 which extends radially outwards.

In this embodiment, the prosthesis is held only by the parts of the base ring and the fixing ring surrounding the heart tissue.

The fixing ring 14 of the heart valve prosthesis shown in Figs. 8 and 9 is provided with a cylindrical portion 42, round the periphery of which is distributed a series of L-shaped spikes 43. Each spike 43 has a portion 44 connected to the lower part of the segment 42 and pointing radially outwards and an upwardly pointing axial portion 45 with a sharpened end 46. Radially inwardly directed noses 47 of the fixing ring cooperate with annular grooves 48 on the outside of the connecting portion 9. The outside of the portion 42 and the radial portions 44 of the spikes 43 are covered with a mesh or pore containing substance 49, which has an extended protective fold 50.

In order to fasten the fixing ring to the heart tissue, the heart tissue is pierced by the axial portions 45 of the extended spikes 43 whereupon the ends 46 are bent over radially inwards. The valve body is put in place and held by engaging the noses 47 in the grooves 48. The protective fold 50 is then laid round radially outwards.

In order to guard against the formation of clots on the auricle (low pressure) side of the prosthesis, the pores or meshes are closed on the outer face of the protective fold 50 by a layer 51. The layer 51 may for example consist of silicone rubber. Rubber paste R 113 VE of the firm Wacker-Chemie and Wacker-Silicon-Kautschuke Dispersion I VE have been found specially suitable.

WHAT I CLAIM IS:—

1. A heart valve prosthesis with a valve body, a valve member movable with respect to the valve body, and a fixing ring serving for the attachment of the prosthesis to the heart tissue the fixing ring being initially separate from but capable of being united with the valve body.

2. A heart valve prosthesis as claimed in claim 1 in which the valve body and the fixing ring are detachably connected to one another.

3. A heart valve prosthesis as claimed in claim 1 or 2, in which the fixing ring can be attached as such to the natural heart tissue.

4. A heart valve prosthesis as claimed in claim 1, 2 or 3, in which the fixing ring is provided with a number of recesses distributed over its periphery, through which a surgical thread can be passed for sewing the fixing ring to the natural heart tissue.

5. A heart valve prosthesis as claimed in claim 1, 2 or 3, in which the fixing ring is provided with spikes which can be clamped to the natural heart tissue.

6. A heart valve prosthesis as claimed in claim 1 or 2, in which the fixing ring together with parts of the valve body forms an annular clamp, in which the natural tissue directly bordering on the prosthesis may itself be encompassed and/or in which a supporting ring connected to the natural tissue may be received.

7. A heart valve prosthesis as claimed in any of claims 1 to 6, in which the valve body is provided with a connecting projection cooperating with the fixing ring and having a smaller external diameter than a base ring of the valve body containing the valve seat.

8. A heart valve prosthesis as claimed in claim 7, in which the fixing ring or the connecting projection is provided with springy barbs, which can be engaged in corresponding depressions in the connecting

projection or fixing ring respectively.

9. A heart valve prosthesis as claimed in claim 7 or 8, in which the part of the fixing ring facing the valve member is divided into springy prongs by axial notches, the free ends of which prongs carry barb-like noses directed radially inwards, and the connecting projection at its end facing the valve member is provided with an annular groove for the reception of the noses of the springy prongs of the fixing ring.

10. A heart valve prosthesis as claimed in claim 9, in which the outer surface of the connecting projection is of frusto-conical form broadening from the free connecting end to the end adjacent the valve member.

11. A heart valve prosthesis as claimed in claim 9 or 10, in which the connecting projection is provided with one or more additional safety grooves.

12. A heart valve prosthesis as claimed in any of claims 7 to 11, in which the external diameter of the connecting projection and the internal diameter of the fixing ring are so proportioned that a surgical thread passed round the fixing ring and used for sewing the fixing ring to the natural heart tissue can be clamped between these two structural parts on fastening them together.

13. A heart valve prosthesis as claimed in any of claims 7 to 12, in which material containing meshes or pores is attached to the fixing ring and/or the base ring and/or the supporting ring for the natural body tissue to grow into.

14. A heart valve prosthesis as claimed in claim 13, in which the material containing meshes or pores partly envelopes the fixing ring and is twisted or folded together to a loose pad on the outside of the fixing ring.

15. A heart valve prosthesis as claimed in claim 14, in which the fixing ring has a radially outwardly directed annular flange on the side remote from the base ring and the pad is held in the angle between the annular flange and the axial part of the fixing ring.

16. A heart valve prosthesis as claimed in claim 15, in which a plastic clot-preventing substance is provided on the outer side of the radial annular flange of the fixing ring or the meshed material present thereon.

17. A heart valve prosthesis as claimed in any of claims 7 to 16 which is provided with a screen which can be clamped between the base ring and the fixing ring.

18. A heart valve prosthesis as claimed in any of claims 7 to 17 in which a ball cage encompassing a valve ball is affixed to the base ring, and one or more of the struts of the ball cage terminate at a distance from the base ring.

19. A heart valve prosthesis constructed substantially as herein described with reference to and as illustrated in Figs. 1 to 4 of the accompanying drawings.

20. A heart valve prosthesis constructed substantially as herein described with reference to and as illustrated in Fig. 5 of the accompanying drawings.

21. A heart valve prosthesis constructed substantially as herein described with reference to and as illustrated in Figs. 6 and 7 of the accompanying drawings.

22. A heart valve prosthesis constructed substantially as herein described with reference to and as illustrated in Figs. 8 and 9 of the accompanying drawings.

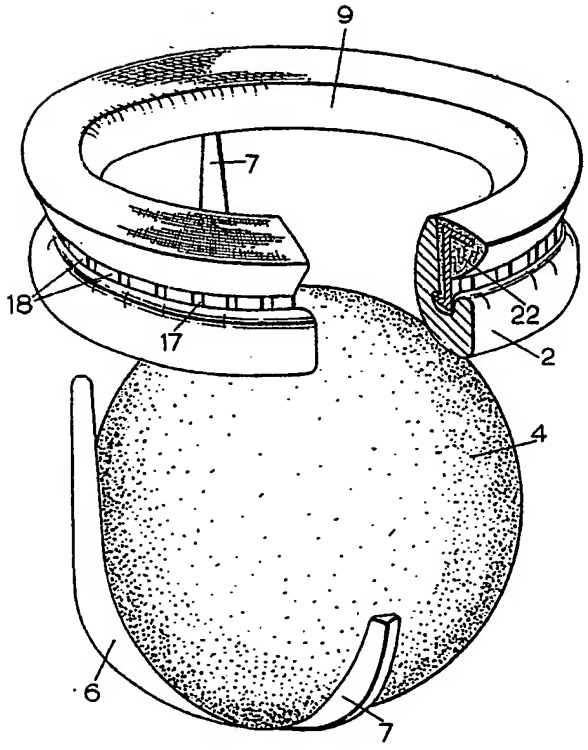
23. A heart valve prosthesis as claimed in claim 1 and constructed substantially as hereinbefore described.

W. P. THOMPSON & CO.,
12, Church Street,
Liverpool, 1.
Chartered Patent Agents.

Sheerness: Printed for Her Majesty's Stationery Office by Smiths Printers and Duplicators.—1967.
Published at the Patent Office. 25 Southampton Buildings, London, W.C.2, from which copies may be obtained.

1093599 COMPLETE SPECIFICATION
7 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheet 1

—FIG.1.—



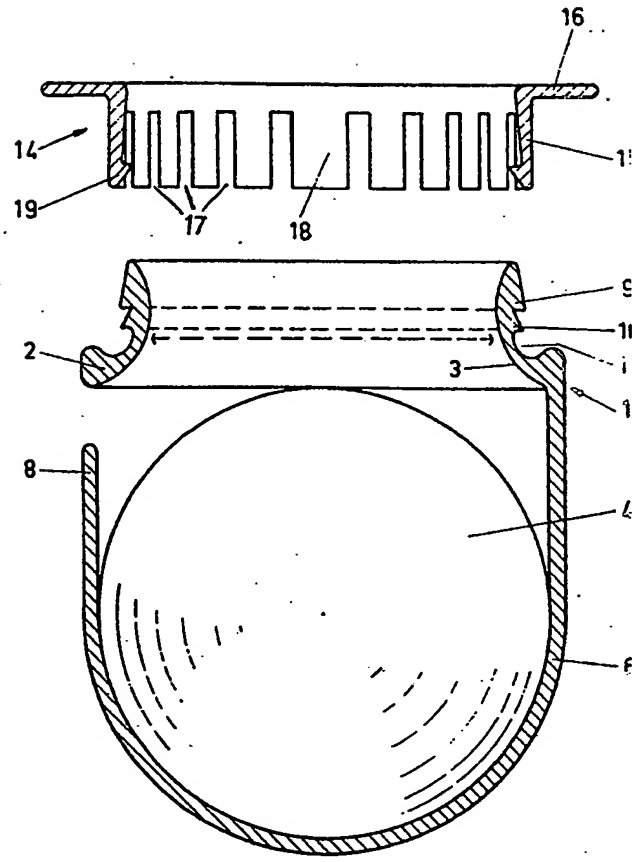


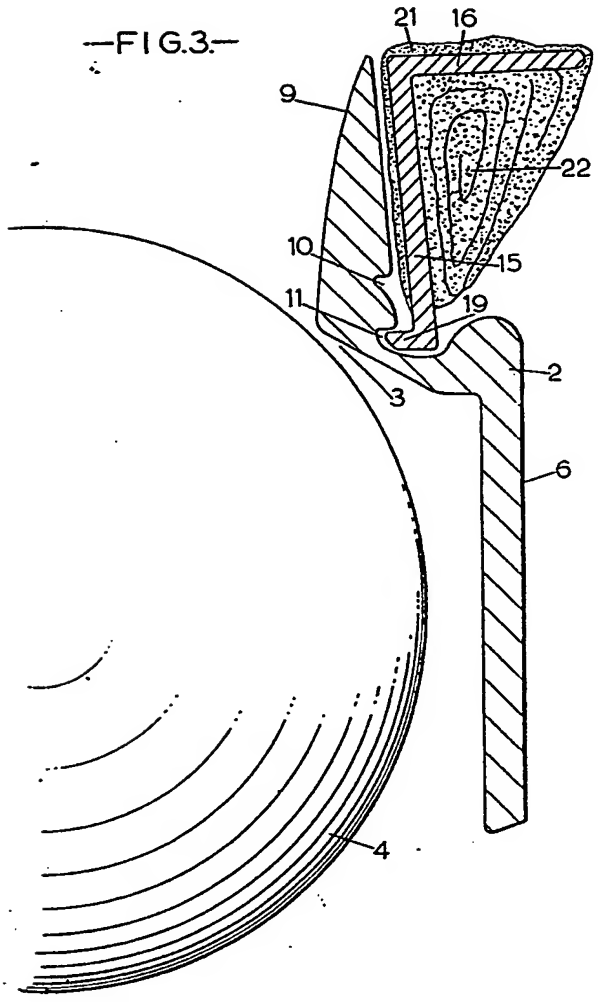
Fig. 2

1093599 COMPLETE SPECIFICATION

7 SHEETS *This drawing is a reproduction of the Original on a reduced scale*

Sheets 2 & 3

—FIG.3.—



-15
-9
-10
-11
-1
-4
-6

1093599 COMPLETE SPECIFICATION
7 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheets 2 & 3

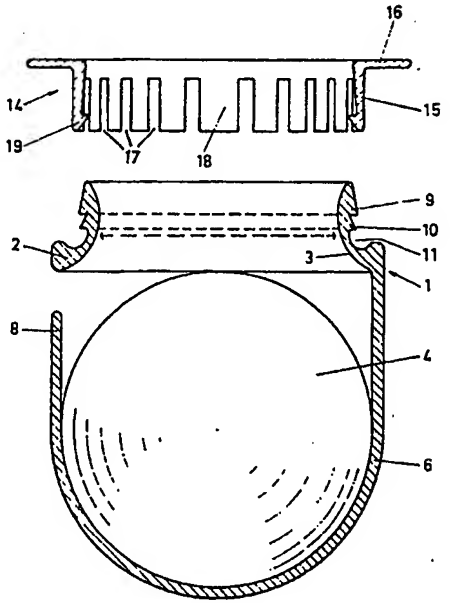
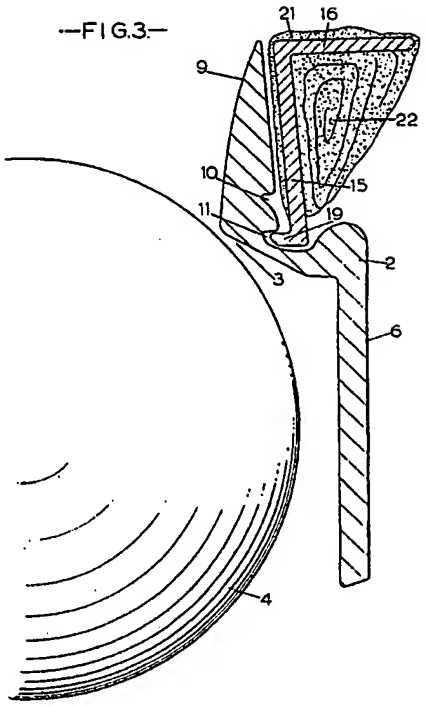
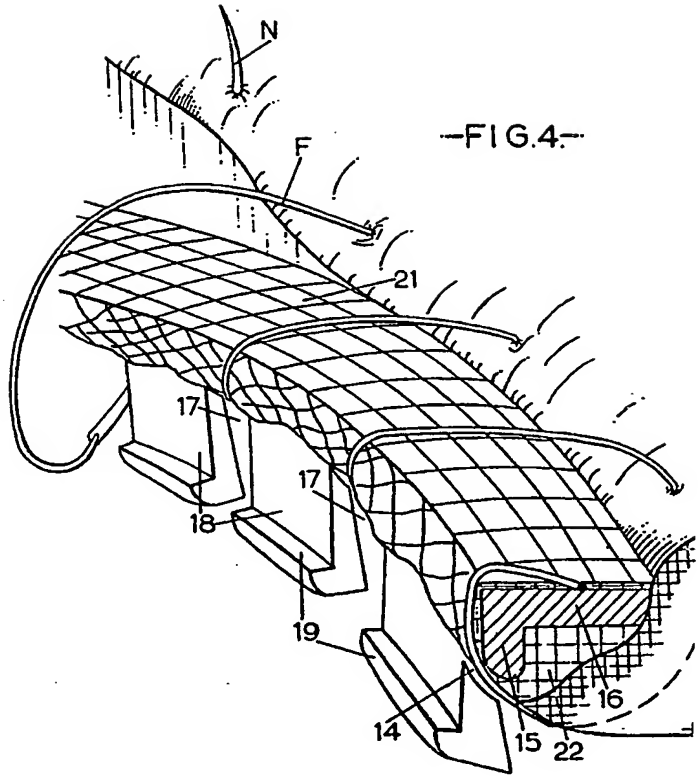


Fig. 2

—FIG.3.—





-FIG.4-

1093599 COMPLETE SPECIFICATION

7 SHEETS *This drawing is a reproduction of the Original on a reduced scale*

Sheets 4 & 5

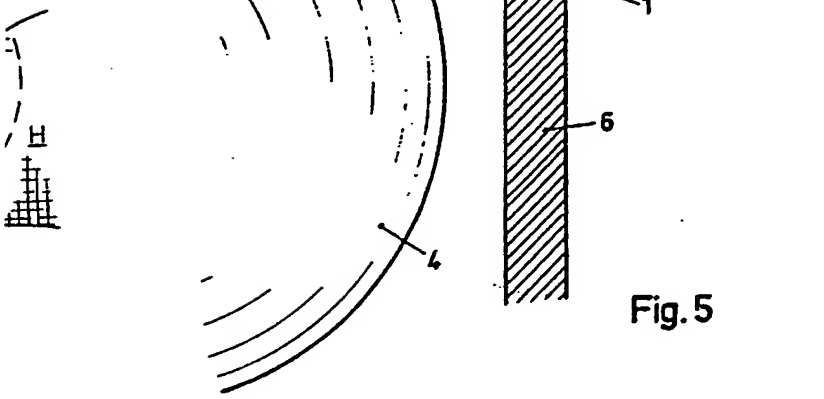
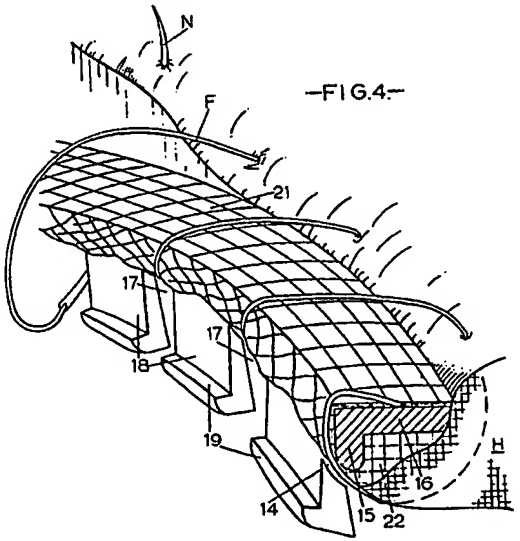


Fig. 5

1093599 COMPLETE SPECIFICATION
7 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheets 4 & 5



-FIG.4.-

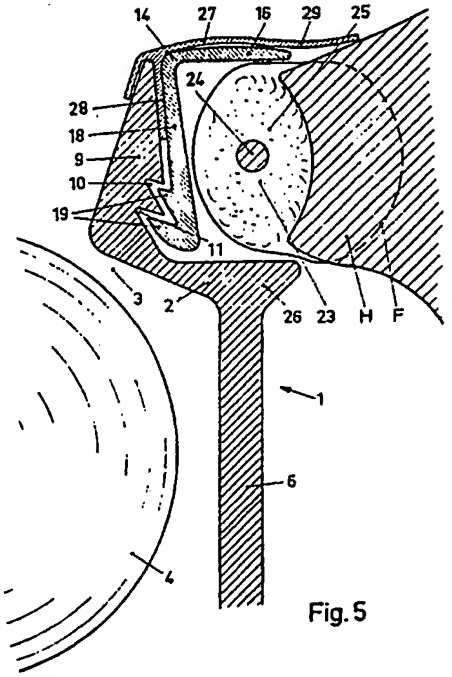


Fig.5

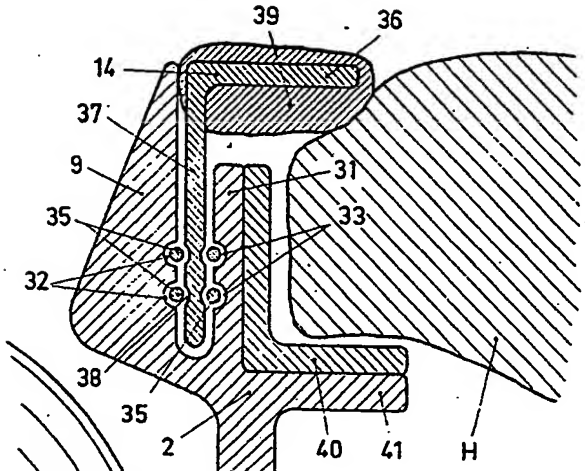


Fig. 6

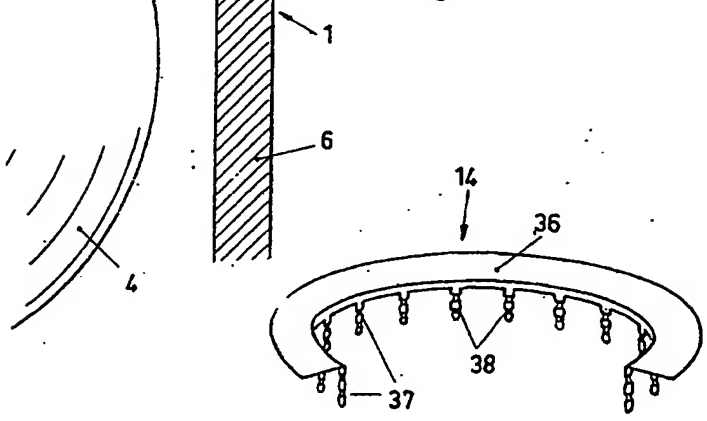


Fig.7

1093599 COMPLETE SPECIFICATION
7 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheets 6 & 7

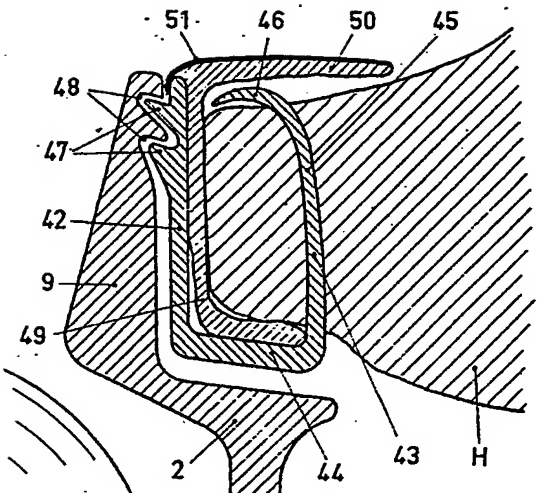


Fig. 8

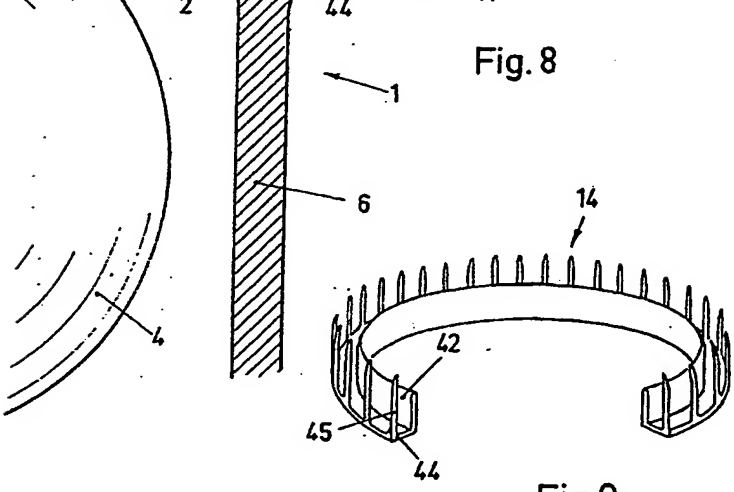


Fig.9

1093599 COMPLETE SPECIFICATION
7 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheets 6 & 7

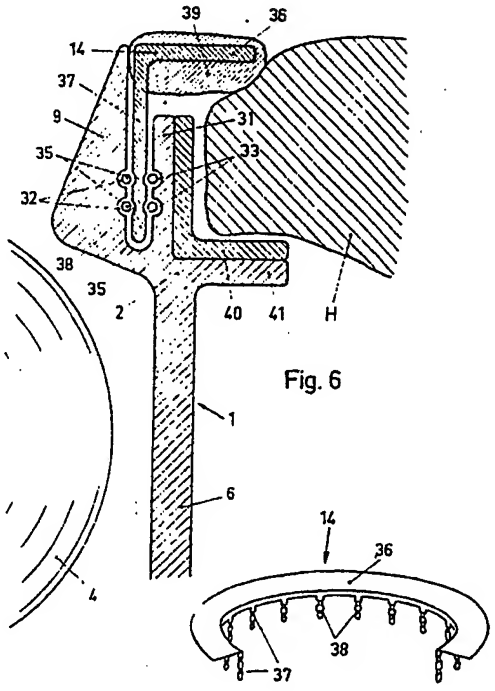


Fig. 6

Fig.7

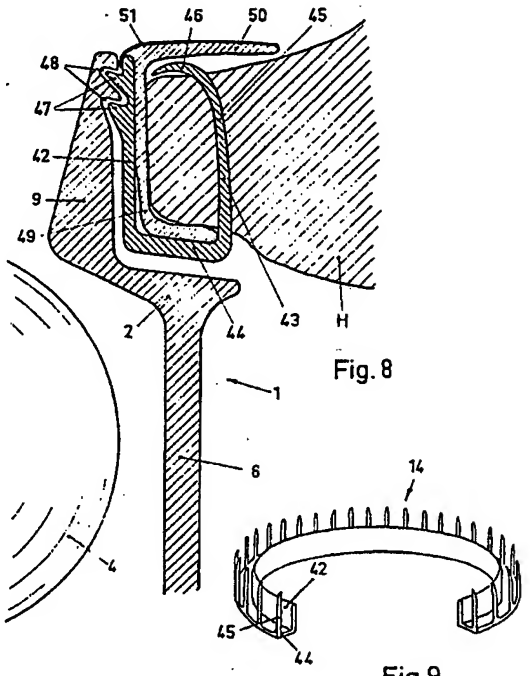


Fig. 8

Fig.9